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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/725,324	11/28/2000	Steven R. Leong	0152.210US	5894

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/725,324	LEONG ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *184-190,201,204 and 207-216* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *184-190,201,204 and 207-216* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3142005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 2/22/05, has been entered.

Amended claims 184-189, 204, 208 and new claims 209-216, filed 2/22/05, are acknowledged.

Claims herein under examination are 184-190, 201, 204, and 207-216.

Double Patenting

Applicant is advised that should claims 184, 188, 201, 204, and 208-211, and 213-216 be found allowable, claims 184, 188, 201, 204, 208-211, 213-216 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 208 appears to be reciting a property of the isolated or recombinant polypeptide of instant claim 184. It is noted that properties are inherent to a product and do not further limit the structure of the product.

Claim 209 appears to be reciting a property of the isolated or recombinant polypeptide of instant claim 188. It is noted that properties are inherent to a product and do not further limit the structure of the product.

Claim 213 is a duplicate of claim 201, because both contain the same polypeptide and a carrier. The composition of claim 213 comprises the polypeptide of claim 208 that appears to be reciting a property of the isolated or recombinant polypeptide of instant claim 184, but does not further limit the structure of the isolated or recombinant polypeptide of instant claim 184. It is noted that properties are inherent to a product and do not further limit the structure of the product.

Claim 214 is a duplicate of claim 204, because both contain the same polypeptide and a p35 polypeptide subunit of human interleukin-12. The composition of claim 214 comprises the polypeptide of claim 208 that appears to be reciting a property of the isolated or recombinant polypeptide of instant claim 184, but does not further limit the structure of the isolated or recombinant polypeptide of instant claim 184. It is noted that properties are inherent to a product and do not further limit the structure of the product.

Claim 215 is a duplicate of claim 210, because both contain the same polypeptide and a carrier. The composition of claim 215 comprises the polypeptide of claim 209 that appears to be reciting a property of the isolated or recombinant polypeptide of instant claim 188, but does not further limit the structure of the isolated or recombinant polypeptide of instant claim 188. It is noted that properties are inherent to a product and do not further limit the structure of the product.

Claim 216 is a duplicate of claim 211, because both contain the same polypeptide and a p35 polypeptide subunit of human interleukin-12. The composition of claim 216 comprises the polypeptide of claim 209 that appears to be reciting a property of the isolated or recombinant polypeptide of instant claim 188, but does not further limit the structure of the isolated or recombinant polypeptide of instant claim 188. It is noted that properties are inherent to a product and do not further limit the structure of the product.

Claims Rejected Under 35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF SCOPE OF ENABLEMENT

Claims 208, 209, and 213-216 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 4-fold increases in T cell proliferation using a certain combination of polypeptides, does not reasonably provide enablement for a 4-fold increase under any conditions as currently encompassed by the broadly stated limitations of the polypeptides of claims 184 and 188 in the presence of any p35 subunit of human interleukin-12 compared to any other combination of p40 and p35 subunits human interleukin-12. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification (page 16, first paragraph) states that SEQ ID NO: 1 is a modified p40 nucleic acid sequence that encodes SEQ ID NO: 8. The specification on page 30, starting on last paragraph, teaches testing for T-cell proliferation activities in culture supernatants of cells co-expressing various exemplified p40 nucleic acids plus wild-type p35 nucleic acid in comparison to supernatants of control cells co-expressing wild type p40 plus wild type p35 nucleic acids, as shown in Figures 2-6. The specification states that the data show that cells co-expressing a modified p40 nucleic acid with a wild type p35 nucleic acid secrete biologically active protein with 4-fold to as much as 64-fold higher T-cell proliferative activity than cells expressing wild type p40 plus wild type p35 nucleic acids. Table 1 shows C2-22 (SEQ ID NO: 1 which encodes SEQ ID NO: 8) with a ~32 to 64 fold increase compared to control. On page 33 (first full paragraph) of the specification, it is stated that relative amounts of modified heterodimeric protein and wild-type heterodimeric protein were quantitated with modified nucleic acids tending to promote enhanced production of modified heterodimers as compared to wild-type

heterodimers. The specification states on page 34, line 11, that purified C2-22(SEQ ID NO: 1)/wild type p35 heterodimer exhibited about a 4-fold higher proliferative activity than the compared control of wild type p40/wild type p35, as seen in Figure 9. Claims 208 and 209 state that there is a 4-fold increase in T cell proliferation with the polypeptide of instant claims 184 and 188, respectively, in the presence of a p35 polypeptide subunit of human interleukin-12 compared to the proliferation of T cells of a p40 and p35 polypeptide subunits of human interleukin-12. It is noted that SEQ ID NO: 8 could represent the latter mentioned p40 polypeptide subunit above, such that the comparison could essentially be a duplication resulting in no 4-fold increase. It is also noted (see Table 2) that a comparison of (A) C2-22 (SEQ ID NO: 1)/R2-42 (SEQ ID NO: 16, modified p35 subunit) heterodimer as well as (B) C2-22(SEQ ID NO: 1)/R2-157 (SEQ ID NO: 24, modified p35 subunit) heterodimer both show ~ 8-fold increase compared to wild types p40 and p35 subunit heterodimers, such that a comparison of (A) and (B) would not produce a 4-fold increase. The specification on page 35 states that the SEQ ID NO: 8 involved heterodimer (C2-22/R2-571) shows about 8 times greater T-cell proliferative activity than the wild type p40/p35 heterodimer. While there is written support for 4-fold increases, it is noted that there are no experimental examples that specifically state an exact 4-fold increase as recited in these claims. Further experimentation would be required to determine which heterodimer combinations resulted in exact 4-fold increases over other heterodimers. Thus, claims 208 and 209 do not appear to be fully enabled for every modified and wild type heterodimer combinations providing 4-fold increases, as currently stated in these claims.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 204, 208, 209, and 211-216 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 184 and 188 (lines 3 of each), 208 (line 2), and 209 (lines 1-2) recite the phrase "the polypeptide" which lacks clear antecedent basis. It is unclear if the phrase is referring to the "isolated or recombinant polypeptide" in line 1 of claims 184 or 188 or to the p35 polypeptide in lines 3 and 2, respectively, of claims 184 and 188. It is noted that the current language of the claims may be interpreted as identification of SEQ ID NO: 8 as the p35 polypeptide, while SEQ ID NO: 8 is stated in the specification as being a modified p40 polypeptide. Claims 185-187, 189-190, 201, 204, 207, 210-216 are also rejected due to their dependency from claims 184, 188, 208, and 209.

Claims 208 and 209 appear to be reciting a method step involving properties of the product. It is unclear what limitation is intended by the recitation of the intended use to further limit the product. It is unclear if the claim is a method step or if it is attempting to merely recite an inherent property of the product. It is noted that neither of the two above circumstances appear to further limit the structure of SEQ ID NO: 8 as claimed in claims 184 and 188,

respectively. Claims 213-216 are also rejected due to their dependency from claims 208 and 209.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

Marjorie A. Moran
4/21/05

April 19, 2005

MARJORIE A. MORAN
PRIMARY EXAMINER